

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.	: 7,539,530	Art Unit	: 3768
Issued	: May 26, 2009	Examiner	: ROZANSKI, Michael T.
Serial No.	: 10/646,271	Customer No.	: 06449
Applicant	: Jay D. CAPLAN, et al.	Confirmation No.	: 9460
Filed	: August 22, 2003	Attorney Docket No.	: 3619-0305.US
Title	: METHOD AND SYSTEM FOR SPECTRAL EXAMINATION OF VASCULAR WALLS THROUGH BLOOD DURING CARDIAC MOTION		

**REQUEST FOR RECONSIDERATION OF DECISION ON PETITION TO CORRECT
PATENT TERM ADJUSTMENT**

Director of the United States Patent
and Trademark Office
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In a Decision on Request for Reconsideration of Patent Term Adjustment (“Decision”) dated September 16, 2009, the United States Patent and Trademark Office (“Office”) dismissed Patentees’ Petition to Correct Patent Term Adjustment under 37 C.F.R. § 1.705(d). The Office confirmed that U.S. Patent No. 7,539,530 (“the ‘530 patent”, misidentified in the Decision as Patent No. 7,535,457) is entitled to 830 days of patent term adjustment (PTA) due to examination delay, otherwise referred to as “A delay.” The Office, however, did not follow the Patentee’s request to apply the rule set forth in *Wyeth v. Dudas*, 580 F.Supp. 2d 138 (D.D.C. 2008) with respect to the calculation of “overlap” of “A delay” and “B delay.” Patentee respectfully maintains that the ‘530 patent is entitled to an additional 638 days of patent term adjustment due to “B delay,” otherwise referred to as three-year delay. The legal issue concerning the calculation of such “overlap” is identical to the legal issue decided in *Wyeth*. Following the *Wyeth* precedent would result in a total PTA calculation of 1294 days, for the reasons detailed in Patentee’s Petition to Correct Patent Term Adjustment filed on June 26, 2009.

The Office acknowledged that Patentees requested recalculation of PTA according to the rules set forth in *Wyeth*. Decision at page 1. However, that acknowledgement was the sole

mention of *Wyeth* in the entire Decision. Most of the Decision puts forth the Office's legal argument that had been considered and rejected by the court in *Wyeth*. The Office's arguments appear to be presented anew in the Decision as though the *Wyeth* case has no relevance to the present PTA calculation.

The statute governing PTA instructs a patentee dissatisfied with a determination made by the Director to pursue a civil action against the Director in the United States District Court for the District of Columbia. 35 U.S.C. § 154(b)(4)(A). The statute makes clear that the District Court for the District of Columbia is the sole court with jurisdiction to hear such PTA challenges. It was under this statutory provision that *Wyeth* brought its action against the Director and prevailed on the exact same legal issue that is in contention for the present patent. Still, and despite the previous adverse ruling on this legal issue, the Office in the present Decision has ignored the clear ruling of the only district court with authority to consider PTA challenges.

As the identical legal issue of the present PTA challenge has already been decided by the only district court with authority to consider PTA challenges, Patentees submit that the Office should either follow the law as interpreted by that court or stay a final decision in this matter until the ongoing appeal of the *Wyeth* decision has been decided by an appellate court. Subsequent to the *Wyeth* decision, numerous patentees have filed suits in the District Court for the District of Columbia challenging PTA calculations based on the same legal issue presented in *Wyeth*. Because the District Court for the District of Columbia has already decided the issue and the Office has appealed that decision to the Federal Circuit, the Office and the plaintiffs have requested stays of most or all of those litigations pending the outcome of that appeal. Fairness dictates that the Office act in a consistent manner during the present administrative process. Given its current legal posture, it would be fundamentally unfair for the Office to render a final ruling on this issue when its interpretation of the statute and rules have been rejected by the court and it is currently seeking to have that adverse ruling reversed on appeal.

The district court with sole jurisdiction to hear PTA challenges has squarely rejected the Office's interpretation of this statutory provision. "While deference is to be given to an agency's interpretation of the statute it administers [citations omitted], it is the courts that have the final

word on matters of statutory interpretation.” *Ithaca College v. NLRB*, 623 F.2d 224,228 (2d Cir. 1980) (citing *inter alia Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177, 2 L.Ed. 60 (1803)). By comparison to the Office's apparent disregard for the precedent of the District Court for the District of Columbia in calculating PTA for the present patent, the National Labor Relations Board has been admonished for its practice of refusing to follow unfavorable decisions from the courts in instances where it was likely that a case at issue would come up for review before the very court with which the Board disagrees.

Of course, we do not expect the Board or any other litigant to rejoice in all the opinions of this Court. When it disagrees in a particular case, it should seek review in the Supreme Court. During the interim before it has sought review or while review is still pending, it would be reasonable for the Board to stay its proceedings in another case that arguably falls within the precedent of the first one. However, the Board cannot, as it did here, choose to ignore the decision as if it had no force or effect. Absent reversal, that decision is the law which the Board must follow. The Board cites no contrary authority except its own consistent practice of refusing to follow the law of the circuit unless it coincides with the Board's views. This is intolerable if the rule of law is to prevail.

Id. Similarly, absent a reversal by the Federal Circuit or the Supreme Court, the Office cannot act in a manner that ignores the *Wyeth* decision as if it had no force or effect.

Patentees request that the Office follow the legal authority of *Wyeth* and increase total PTA for the ‘530 patent to 1294 days (for the same reasons detailed in Patentee’s Petition to Correct Patent Term Adjustment filed on June 26, 2009). If the Office is unwilling to follow the ruling in *Wyeth* while the appeal of that decision is ongoing, then it should, at a minimum, follow the rationale it has put forth recently in PTA litigations pending before the District Court for the District of Columbia and stay a final decision on this matter until the *Wyeth* appeal has been completed. It is the courts, and not the Office, that must have the final word on this matter of statutory interpretation.

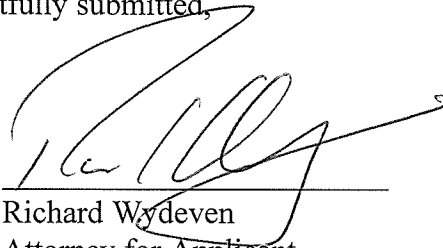
Although no fee is believed due, authorization is hereby given to charge any fee deemed necessary in connection with the filing of this paper, or credit any overpayment, to Deposit Account No. 02-2135.

Respectfully submitted,

Date:

11/10/09

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